However, please be advised that this is only a general rule, and in the present case the structure of the product resulting from ion incorporation by ion beam implantation or cathodic arc deposition is most appropriately described by reference to these methods. Moreover, please be advised that the product resulting from ion incorporation by ion beam implantation or cathodic arc deposition can only be suitably described in terms of these methods. Therefore, the claim 1 language is the only adequate means of defining Applicants' invention.

Specifically, the methods of ion beam implantation and cathodic are depositions as described in claim 1 dictate the ultimate <u>positioning</u> of the ions which are incorporated by such methods in or on the surface of bone implant. In particular, it is considered that ions become placed <u>between the molecular structures of the bioactive material surface (e.g., a hydroxyapatite coating)</u>. (This is analogy to the relationship between metal ions in some types of alloy). This is in stark contrast to other methods of ion incorporation, such as those that employ chemical combination and substitution methods.

As a separate point, if the technique of ion implantation is used on a crystalline structure, such a technique will create damage which disrupts the crystalline structure of the modified surface layer, the extent of damage depending on the structure of the material being implanted. As with the positioning of the ions referred to above, such alteration in structure can only be suitably described by the technique itself rather than the resulting structure.

Based on the foregoing withdrawal of the §112 second paragraph rejection of claims 1-14 and 20-24 is respectfully requested.

Claims 1-2, 7-9, 11-19 and 21-23 stand rejected as allegedly being anticipated by Constantz. This rejection is respectfully traversed.

Constantz discloses an implant having a hydroxyapatite coating. However, in contrast to claim 1 of the present application, Constantz does not disclose a method of incorporating ions into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition. Moreover, Constantz does not disclose <u>any</u> method of incorporating ions into or onto the surface of the bone implant. As mentioned above, such methods directly affect the resulting structure of

the bone implant. The methods taught by Constantz would not provide a bone implant having the surface claimed in present claim 1.

Constantz describes a method in which soluble sources of calcium and phosphate are combined under controlled conditions nucleation and crystal growth with the end result of forming uniform coatings, on "porous structures' for bone "ingrowth". By contrast, the implant disclosed in the present invention is formed from the modification of an already formed coating, which is not on a porous structure. The present application relates to a surface (or immediate sub-surface to say 100 nm) modification of a pre-existing layer. Thus, the process of Constantz results in a uniform coating and would not produce the surface (or sub-surface) modification resulting from the ion implantation or cathodic are deposition referred to in the present claims.

The Office Action indicates that Constantz refers to "substitution" of calcium cations with other ions (column 2, lines 52 and 53). However, the context of Constantz, such substitution implies chemical combination. Constantz does not refer to any specific method of substitution of calcium ions. Moreover, incorporation ions into or onto the surface of a bone implant by ion beam implantation/embedding or cathodic arc deposition (as this feature is recited in claim 1 it is not considered to be such a substitution method). Accordingly, an implant in which calcium ions have been substituted with other ions cannot anticipate the implant disclosed in claim 1.

In view of the above, it is clear that Constantz does not disclose or even suggest the product of independent claim 1, and the method of independent claim 15. Furthermore, Constantz does not disclose or suggest a bone implant wherein the ions are incorporated into the surface atomic layers of the bone implant up to a maximum depth of 200nm (as recited in the independent claim 25 presented herein).

Claims 1-2, 7-16 and 21-24 stand rejected as allegedly being anticipated by Natasi et al. This rejection is respectfully traversed.

The Examiner also asserts that claims 1, 2, 7-16 and 21-24 are anticipated by Nastasi. Nastasi discloses a titanium alloy implant having a hydroxyapatite coating. Furthermore, Nastasi

discloses intermixing the titanium alloy with hydroxylapatite and further densifying the hardened layer using non-line-of-sight ion-implantation and/or rapid thermal processing.

However, in contrast to claim 1 of the present application, Nastasi does not disclose incorporating ions from one or more of the groups IIA, IVA, VIIA and transition elements by ion beam implantation or cathodic arc deposition. Indeed, the only ion mentioned by Nastasi is argon.

The Examiner refers to column 5 (lines 25-27) of Nastasi, which states that "other ions may be utilized in the ion implantation technique". However, this general teaching of Nastasi cannot anticipate the specific disclosure of claim 1 for the following reasons.

The present application is concerned with promoting and enhancing bone growth onto an already layer. In contrast, Nastasi addresses a completely different problem, namely, providing a posthetic implant which has improved bonding between the coating of the implant (hydroxylapatite) and the metal of the implant (titanium alloy), thereby preventing delamination and separation of the coating from the alloy (column 2, lines 48-54).

Furthermore, the solutions to the respective problems addressed by the present application and the present application and Nastasi are different. The present application achieves its aim by incorporating into or onto an established layer ions from one or more of the groups IIA, IVA, VIIA and transition elements by ion beam implantation or cathodic arc deposition. By contrast, Nastasi provides a method in which a first sol-gel layer is densified and hardened by non-line-of sight ion beam implantation using argon, to provide mixing of titanium and hydroxyapatite.

The use of ion implantation described in Nastasi is to improve the bonding of the first sol-gel layer to the titanium substrate, and not to promoting and enhancing bone growth from this first layer. This is emphasized in column 3, lines 54-67 of Nastasi, which states that "the first layer of hydroyapaptite is mixed with the substrate by the ions or rapidly thermally annealed, while subsequent layers are heat treated to form layers of decreasing density and larger crystallization, with the outermost layers being suitable for bone ingrowth". Thus, is clear from

this passage (and the claims) that Nastasi does not recognize that the application of ion implantation to incorporate ions into or onto the surface of a bioactive material will promote and enhance bone growth. If this were the case, then Nastasi would not preclude the application of ion implantation into subsequent layers (i.e., the layers from which bone growth will occur from). In this regard, we also refer you to the claims of Nastasi which further demonstrate that is only the first (i.e., inner most) layer which is subjected to ion implantation.

By contrast, in the present invention, the ions are incorporated into or onto the surface of the bone implant by ion beam implantation, to enable the promotion and enhancement of bone growth from this surface. In this regard, the present inventors have recognized that incorporation of ions from IIA, IVA, VIIA and transition elements by ion beam implantation or cathodic arc deposition will best serve this purpose. Nastasi does not disclose such a step, nor does Nastasi recognize the advantages of such a step. While Nastasi mentions that other ions may be employed there is no mention of which ions may be employed or of any potential advantage in employing any such other ions. Furthermore, any other such ions would <u>not be applied to the surface of the implant</u> and so would <u>only</u> (if anything) serve to improve the bonding between the coating of the implant and its substrate and would <u>not</u> increase bone growth. Accordingly, the method taught by Nastasi would not provide a bone implant having the surface claimed in present claim 1.

In view of the above, the general teach of Nastasi cannot anticipate the subject matter of product claim 1 and method claim 15. Furthermore, Nastasi does not disclose or suggest a bone implant in which the ions are incorporated into the surface atomic layers up to a maximum depth of 200 nm (as recited in the independent claim 25, newly presented).

Claims 3-6, 10, 17-20 and 24 stand rejected under 35 U.S.C. §103 as being unpatentable over Constantz. This rejection is also respectfully traversed.

Particularly, it would not be obvious to modify the teaching of Constantz to arrive at the present invention since Constantz does not disclose or suggest an implant having ions which have been incorporated by the technique of ion beam ionisation/embedding or cathodic arc deposition. The only reference in Constatz to the hydroxyapatite being modified to incorporate

other ions is in column 2, lines 46-55. However, as mentioned above, Constantz does not disclose any specific method by which these ions may be incorporated into hydroyapatite. In view of the number of ways of incorporating ions into hydroyapatite, it would not be at all obvious from the teaching of Constantz to use the techniques recited in independent claims 1 and 15 of the present application.

Furthermore, the method of Constantz would teach the skilled person away from using ion beam ionisation or cathodic arc deposition. As mentioned above, Constantz refers to "substitutions" which implies "chemical combination", a process which is very much distinct from ion beam ionisation or cathodic arc deposition.

In addition, Constantz does not address the problem of promoting and enhancing bone growth onto an already established layer. In contrast, Constantz states that "these substitutions will influence the *in vivo* dissolution behavior of the coating which may be resorbable or not resorbable". Thus, since Constantz does not recognize that the use of ions selected from groups IIA, IVA, VIIA and transition elements enhance bone ongrowth properties [further recognized by the fact that of all the further ions suggested by Constantz, only one (fluorine) would fall within the ions listed in claim 1], the skilled addressee would not consider optimizing the incorporation of these ions in order to enhance bone ongrowth by ion beam ionisation or cathodic arc deposition.

Based thereon, withdrawal of the rejection of claims 3-6, 10, 17-20 and 24 based on Constantz is therefore respectfully requested.

Finally, claims 3-6, 17-20 and 24 stand rejected under 35 U.S.C. §103 based on Nastasi et al. This rejection is also respectfully traversed.

Particularly, for the reasons set forth in our traversal of claims 1-2, 7-16 and 21-24 on novelty grounds the references does not teach or suggest the invention. Moreover, it would not be obvious to use the teaching of this document to incorporate one or more ions selected from groups IIA, IVA, VIIA and transition elements into or onto the surface of a bone implant by ion

beam ionisation or cathodic arc deposition. Therefore, withdrawal of the §103 rejection of claims 3-6, 17-20 and 24 based on Nastasi is respectfully requested.

Based on the foregoing, it is believed that all the rejection and objections have been overcome. A Notice of Allowance is therefore respectfully believed to be in order.

Respectfully submitted,

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Attachment:
Appendix

APPENDIX

6. (Amended) ~~A~~ The bone implant as claimed in any one of the preceding claims wherein the ions are present at a level of between 1×10^{10} and 1×10^{18} ions per cm^2 of the surface.

7. (Amended) ~~A~~ The bone implant as claimed in any one of the preceding claims, wherein the ions are selected from one or more groups of the periodic table consisting of groups IIA, IVB, VIB, VIIB, VIII, IB, IIB, IVA AND VIIA.

8. (Amended) ~~A~~ The bone implant as claimed in claim 7, wherein the ions comprise one or more of the following:

> magnesium, calcium, strontium, titanium, chromium, manganese, iron, copper, zinc, silicon and fluorine ions.

9. (Amended) ~~A~~ The bone implant as claimed in claim 7, wherein the ions incorporated into the surface of the bone implant are from one or more of the groups of the periodic table consisting of groups IIA, VIIB, IIB, IVA AND VIIA.

10. (Amended) ~~A~~ The bone implant as claimed in any one of the preceding claims, wherein the ions comprise magnesium, manganese, zinc or silicon ions.

11. (Amended) ~~A~~ The bone implant as claimed in any one of the preceding claims comprising a body portion coated with a bioactive material coating.

12. (Amended) ~~A~~ The bone implant as claimed in claim 11, wherein the body portion is formed of a metal or a metal alloy~~, preferably a titanium alloy~~.

13. (Amended) ~~A~~ The bone implant as claimed in any one of claims 1 to 10, wherein the bone implant substantially comprises a bioactive material.

14. (Amended) ~~A~~ The bone implant as claimed in claim 13, wherein the bone implant is in granular form.

20. (Amended) The method as claimed in any one of claims ~~14 to 19~~15, wherein the ions are present at between 1 x 10^{10} and 1x 10^{18} ions per cm^2 of the implant surface.

21. (Amended) The method as claimed in any one of claims ~~14 to 20~~15, wherein the ions ~~are selected from one or more groups of the periodic table consisting of groups IIA, IVB, VIB, VIIB, IB, IIB, IVA AND VIIA.~~comprise one or more of the following:

> magnesium, calcium, strontium, titanium, chromium, manganese, iron, copper, zinc, silicon and fluorine ions.